



EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to proanthocyanidins in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to proanthocyanidins in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Pharmatoka, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to a Urell® product containing cranberry (*Vaccinium macrocarpon*) juice powder standardised for proanthocyanidins (PAC) content and bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells. The food that is the subject of the health claim is PAC in Urell®. The Panel considers that the food constituent, PAC in Urell®, which is the subject of the claim, is sufficiently characterised. The Panel considers that reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells is a beneficial physiological effect. No human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. The Panel concludes that a cause and effect relationship has not been established between the consumption of proanthocyanidins in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

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KEY WORDS

Proanthocyanidins, cranberry, *Vaccinium macrocarpon*, Urell®, urinary tract, health claims

¹ On request from the Competent Authority of France following an application by Pharmatoka, Question No EFSA-Q-2012-00700, adopted on 10 July 2013.

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SUMMARY

Following an application from Pharmatoka, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to proanthocyanidins in cranberry and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application includes a request for the protection of proprietary data.

The food that is the subject of the health claim is Urell®, a food supplement containing cranberry (*Vaccinium macrocarpon*) juice powder standardised for its content in proanthocyanidins (PAC). The food constituent which is responsible for the claimed effect is PAC in Urell®. The Panel considers that the food constituent, PAC in Urell®, which is the subject of the health claim, is sufficiently characterised.

Upon a request by EFSA, the applicant clarified that the claimed effect is “reduction of the bacterial colonisation of the urinary tract”, and that “inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells” is the mechanism by which the claimed effect is achieved. The target population proposed by the applicant is the general population. The Panel considers that reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells is a beneficial physiological effect.

The applicant identified one human intervention study which investigated the effect of Urell® (36 mg PAC/capsule) on bacteriuria *in vivo* (Bianco et al., 2012, a letter to the editor) as being pertinent to the claim. The Panel considers that owing to major methodological limitations (i.e. inappropriate urine sampling methods, inappropriate handling of mixed microbial positive cultures, and insufficient reporting of the methods used for the identification of pathogenic bacteria), no conclusions can be drawn from this study for the scientific substantiation of the claim.

The applicant also provided one intervention study (Botto and Neuzillet, 2010) on the effects of Urell® in subjects with asymptomatic bacteriuria after radical cystectomy and ileal cystoplasty as supportive evidence for the claim. The Panel agrees with the applicant that the results obtained in patients with radical cystectomy and ileal cystoplasty cannot be extrapolated to the target population (i.e. general population) for this claim.

In addition, the applicant provided two studies on the *ex vivo* anti-adherence properties of urine from subjects consuming Urell® (Lavigne et al., 2008; Howell et al., 2010) as being pertinent to the claim. The Panel considers that these studies do not provide evidence that an inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells in urine from subjects consuming PAC in Urell® is predictive of the occurrence of a clinically relevant inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells in humans *in vivo*.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of proanthocyanidins in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 10/07/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- On 25/07/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 6/12/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 12/12/2012.
- On 27/02/2013, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 05/03/2013 and restarted on 20/03/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 23/03/2013, EFSA received the requested information (which was made available to EFSA in electronic format on 22/03/2013).
- On 24/04/2013, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 13/05/2013 and restarted on 28/05/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 28/05/2013, EFSA received the requested information (which was made available to EFSA in electronic format on 22/05/2013).
- During its meeting on 10/07/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to PAC in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

opinion on the scientific substantiation of a health claim related to PAC in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of PAC in Urell®, a positive assessment of its safety, nor a decision on whether PAC in Urell® is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Pharmatoka, S.A.S, 118 avenue Paul Doumer, 92563 Rueil Malmaison cedex, France.

Food/constituent as stated by the applicant

According to the applicant, the food for which this health claim is made is Urell®, a food supplement containing cranberry juice powder standardised for proanthocyanidins (36 mg/BL-DMAC/capsule).

Health relationship as claimed by the applicant

According to the applicant, the claimed effect is the inhibition of the adhesion of P-fimbriated *E. coli* bacteria to uroepithelial cells. The applicant states that consumption of cranberry products may reduce urinary tract infections (UTI) by preventing uropathogenic bacteria (particularly *Escherichia coli*) from adhering (sticking) to uroepithelial cells that line the wall of the bladder and thus, without adhesion, *Escherichia coli* cannot infect the mucosal surface of the urinary tract.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wordings for the health claim: "Proanthocyanidins from Urell® contribute to support defence against bacterial pathogens in the lower urinary tract", "Urell® contributes to reduce the P-fimbriated *E. coli* adhesion to uroepithelial cells", "Proanthocyanidins from Urell® cranberry product contribute to reduce the P-fimbriated *E. coli* adhesion to uroepithelial cells", "The *in vitro* and *ex vivo* studies conducted with Urell® or with urine from subjects who consumed Urell® show an inhibition of the adhesion of the P-fimbriated *E. coli* bacteria to uroepithelial cells".

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of one tablet per day of Urell® supplying 36 mg/day of proanthocyanidins measured by BL-DMAC. The target population proposed is the general population.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Urell®, a food supplement containing cranberry (*Vaccinium macrocarpon*) juice powder standardised for its content in proanthocyanidins (PAC).

The applicant specifies that the food constituent which is responsible for the claimed effect is PAC in Urell®.

PAC are a group of flavan-3-ols ranging from dimers to polymers. The monomeric flavan-3-ols (catechins and epicatechins) are not considered to be PACs. PAC from different sources differ in the type of (A or B) linkages between the monomeric units. A capsule of Urell® contains 36 mg of PAC measured as procyanidin A2 equivalents by the colorimetric 4-dimethylaminocinnaldehyde (DMAC) method.

Information about the manufacturing process, stability and batch-to-batch variability has been provided.

The Panel considers that the food constituent, PAC in Urell®, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “inhibition of the adhesion of P-fimbriated *E. coli* bacteria to uroepithelial cells”. Upon a request by EFSA, the applicant clarified that the claimed effect is “reduction of the bacterial colonisation of the urinary tract”, and that “inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells” is the mechanism by which the claimed effect is achieved. The target population proposed by the applicant is the general population.

Bacterial adherence to mucosal surfaces is facilitated by fimbriae, which are proteinaceous fibres on the bacterial cell wall (Duguid et al., 1955; Beachey, 1981). Preventing adhesion facilitates urinary flushing of the bacteria, and thereby prevents bacterial colonisation of the urinary tract (Foo et al., 2000).

The Panel considers that reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Medline/Pubmed using the following key words: (i) *Vaccinium macrocarpon*, cranberry, canneberge, (ii) proanthocyanidins, (iii) *Escherichia coli*, urinary tract infection, uropathogens. In addition, companies distributing preparations of *Vaccinium macrocarpon* were asked to provide information about both published and unpublished studies. A manual search of review articles was also performed.

The applicant identified one human intervention study which investigated the effect of Urell® (36 mg PAC/capsule) on bacteriuria *in vivo* (Bianco et al., 2012) as being pertinent to the claim.

The human intervention study was published as a letter to the editor (Bianco et al., 2012) with insufficient information for a full scientific evaluation. EFSA requested the applicant to provide the full study report. Instead, the applicant provided additional information on methodological aspects of the study (i.e. power calculations, methods of randomisation, urine sample collection, steps for performing quantitative urine cultures, statistical methods), and stated that the full study report did not exist. The study was a randomised, double-blind, placebo-controlled dose-finding intervention where 80 female long-term nursing home residents (mean age 89.2 ± 7 years) with history of urinary tract infection (UTI) were randomised (20 subjects per group) to consume three capsules of Urell® (108 mg PAC), two capsules of Urell® and one placebo capsule (72 mg PAC), one capsule of Urell® and two placebo capsules (36 mg PAC), or three placebo capsules (0 mg PAC) for 30 days. Exclusion criteria were total incontinence, warfarin therapy, < 4 weeks residence, chronic indwelling catheter, terminal prognosis, antibiotic therapy, kidney stones, dialysis, cranberry “therapy”, and cranberry “allergy”. The majority of participants were totally dependent on bathing (54 %) and had some bowel (67 %) and bladder (76 %) incontinence. Urine samples for urine cultures and analyses were collected at baseline and then weekly for four weeks (total 5 specimens) as catch specimens. In patients with urine incontinuity, a bed pan was placed below them. The Panel notes that the urine sampling methods used in this study do not ensure sterility of the samples. Of the 73 urine culture analyses performed at baseline, only one had no bacterial growth and eight had less than 10^5 cfu/mL. Subjects were randomised using two strata permuted block randomisation based on the presence or absence of bacterial growth > 10^5 cfu/mL at baseline. The primary outcome of the study was the number of episodes of bacteriuria (defined as more than 10^5 cfu/mL of any bacteria) and pyuria (defined as “any white blood cells seen on microscopic urin-alysis”) at days 7, 14, 21 and 28 of the study. Results were presented and analysed as number of urine samples per intervention groups with “*E. coli* bacteriuria” plus pyuria, with “other bacteriuria” (defined as presence of any pathogen other than *E. coli*) plus pyuria, or with “no growth” (defined as no growth, < 100 000 cfu/mL, > 100 000 cfy/mL but no WBCs, and growth of mixed flora). The Panel notes that mixed microbial positive cultures (111/298 cases = 37 %) were treated as no growth, and that no information was provided on the methods used to identify pathogenic bacteria, either in the publication or by the applicant upon a request from EFSA. The Panel considers that owing to major methodological limitations (i.e.

inappropriate urine sampling methods, inappropriate handling of mixed microbial positive cultures, and insufficient reporting of the methods used for the identification of pathogenic bacteria), no conclusions can be drawn from this study for the scientific substantiation of the claim.

The applicant also provided one intervention study (Botto and Neuzillet, 2010) on the effects of Urell® in subjects with asymptomatic bacteriuria after radical cystectomy and ileal cystoplasty as supportive evidence for the claim. The Panel agrees with the applicant that the results obtained in patients with radical cystectomy and ileal cystoplasty cannot be extrapolated to the target population (i.e. general population) for this claim. The Panel considers that, in the absence of evidence of an effect of PAC in Urell® on bacterial colonisation of the urinary tract in subjects, who are representative of the target population, results obtained in patients with radical cystectomy and ileal cystoplasty cannot be used for the scientific substantiation of the claim.

In addition, the applicant provided two *ex vivo* studies on the anti-adherence properties of urine obtained from subjects consuming Urell® (Lavigne, 2008; Howell, 2010) as being pertinent to the claim. The Panel considers that these studies do not provide evidence that an inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells by urine from subjects consuming PAC in Urell® is predictive of the occurrence of a clinically relevant inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells in humans.

Twelve *ex vivo* studies and eight reviews addressing the anti-adherence activity of human urine following consumption of cranberry products other than PAC in Urell® on uropathogenic *E. coli* strains were also provided as supportive evidence. The applicant also referred to 11 published opinions regarding cranberry products and urinary tract infections (five opinions of the AFSSA/ANSES, one note of the DGCCRF and a study, one guideline of the EAU, one recommendation of the AFSSAPS and three opinions of EFSA). The Panel considers that, in the absence of evidence of an *in vivo* effect of PAC in Urell® on bacterial colonisation of the urinary tract, these references cannot be used for the scientific substantiation of the claim.

The Panel notes that several health claims applications on cranberry products standardised by their PAC content, in which inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells in the urine of subjects consuming cranberry products was demonstrated, have already been evaluated by EFSA (EFSA, 2009; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011, 2013). However, the studies provided in these applications did not establish that inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells demonstrated *ex vivo* predicts the occurrence of a clinically relevant inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells in humans.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of PAC in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food product, proanthocyanidins (PAC) in Urell®, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “reduction of the bacterial colonisation of the urinary tract”, and “inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells” is the mechanism by which the claim effect is achieved. The proposed target population is the general population. Reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of PAC in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated *E. coli* to uroepithelial cells.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on PAC in Urell® pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0358_FR). July 2012. Submitted by Pharmatoka.

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GLOSSARY / ABBREVIATIONS

AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé
ANSES	L'Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail
DGCCRF	Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (French: Directorate General for Competition, Consumer Affairs and Repression of Fraud)
DMAC	4-dimethylaminocinnaldehyde
EAU	European Association of Urology
PAC	proanthocyanidins
UTI	urinary tract infection
WBC	white blood cells